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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,959

02/25/2004

William Toreki

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/786,959	<b>Applicant(s)</b> TOREKI ET AL.	
	<b>Examiner</b> JAMES W. ROGERS	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 60,61,64-68 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-61,64-68 and 70-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/22/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/18/2007 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64 and 65 are indefinite because they depend upon two cancelled claims 63 and 64. To expedite the examination process the examiner interpreted the claims as depending upon claim 60 which is the only independent claim to recite the limitation of matrix metalloproteinase inhibitor. Correction is required by applicants.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 61 is rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al. (US 5,575,993).

Ward teaches the use of ionene polymers containing biologically-active anions, the polymers included in their structure cationic ammonium ions and the anionic biologically active agent included microbiocides and antiseptics including iodine trihalide  $I_3^-$ . See abstract, col 1 lin 6-15, col 3 lin 34-col col 5 lin 45 and claims 1,18,47,49 and 71. Ward also teaches that iodinated ionene polymers eg  $I_3^-$  have a broad spectrum or activity against bacteria and viruses. See col 4 lin 25-66. Ward teaches that the iodinated ionene polymers can be used to impregnate gauze in a bandage to prevent opportunistic cutaneous infections. See col 4 lin 64-66. Regarding the limitations that the anionic antibiotic is ionically associated with the polymer to achieve extended release, since Ward is within applicants claimed scope it will have the same association and release properties as applicants claimed invention.

Claim 61 is rejected under 35 U.S.C. 102(b) as being anticipated by Marlin et al. (US 5,645,827).

Marlin teaches the use of cationic polysaccharide polymers containing quaternary nitrogens to treat infirmaries of the mucosal surface, the polymers contained anionic therapeutic agents including anti-inflammatory and antibiotics. See abstract, col 1 lin 9-12, col 2 lin 6-9, lin 64-col 4 lin 51 and claims 1,5,11 and 12. Regarding the limitations that the anionic antibiotic, anti-inflammatory is ionically associated with the polymer to achieve extended release, since Marlin is within applicants claimed scope it will have the same association and release properties as applicants claimed invention.

Claim 60 is rejected under 35 U.S.C. 102(b) as being anticipated by Schoenfeldt et al. (US 2002/0172708, cited previously).

Schoenfeldt teaches preparations of a non-fibrous porous material in which an absorbing article contains polyionic polymers with polycationic groups including cationic amines in combination with pharmaceutical medicaments (including ilomastat). See abstract, [001], [0016],[0025]-[0027],[0041]-[0042] and [0054]-[0055]. The compositions were disclosed as useful for the treatment of wounds. It is inherent that since the Schoenfeldt application teaches the use of polycationic polymers with amine groups and the claimed active ilomastat in combination the ionic interaction between the active and the polyionic polymer would be the same as applicants claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61 and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batich et al. (US 2002/0177828, cited previously) in view of Ward et al. (US 5,575,993) or alternatively in view of Marlin et al. (US 5,645,827).

Batich discloses a wound dressing comprised of a substrate covalently bonded to polyionic polymers including vinyl or allyl monomers containing quaternary ammonium groups. See Abstr., [0050]-[0060] lin 1-4, claims 1,12-14. Regarding claim 71 Batich discloses the use of diallyldimethylammonium salts where  $Y^-$  is an acceptable anionic counterion,  $Cl^-$  would be an obvious acceptable anionic counterion and Batich disclosed the use of ammonium chlorides within the examples. See examples and claims 1,11,13-14. Regarding claim 72 Batich specifically discloses the inclusion of hemostatic agents. See [0064].

Batich while disclosing that the wound dressing have antimicrobial properties does not disclose the use of anionic antibiotics, analgesics or anti-inflammatory agents.

Ward and Marlin are disclosed above and are used primarily for their disclosures within that cationic polymers were already well known in the art at the time of applicants claimed invention to incorporate anionic antimicrobial compounds.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the anionic antimicrobials of Ward or Marlin to the cationic polymers of Batich because the references are obviously combinable in that they are related to cationic polymers used to treat infection of microbes. Also one of ordinary skill in the art would expect that since the cationic polymers are all related in that they all have cationic ammonium groups in the polymer chain that the anionic antimicrobials of Ward and Marlin could be added to the cationic polymers of Batich and one of ordinary skill would have a reasonably high expectation of success. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 60,64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batich et al. (US 2002/0177828) in view of Schoenfeldt et al. (US 2002/0172708) and in further view of Voorhees et al. (US 2004/0235950 A1), cited previously.

Batich is disclosed above. Batich does not disclose the use of the matrix metalloproteinase (MMP) inhibitors, ilomostat or GM1489.

Schoenfeldt is disclosed above and is used primarily for the disclosure within that cationic polymers were already well known in the art at the time of applicants claimed invention to incorporate ilomastat.

Voorhees discloses compositions and methods for use against acne-induced inflammation and describes the use of ilomastat and GM 1489. See abstr, and [0049].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include ilomastat of Schoenfeldt to the cationic polymers of Batich because the references are obviously combinable in that they are related to cationic polymer formulations for the treatment of wounds. Also one of ordinary skill in the art would expect that since the cationic polymers of Batich and Schoenfeldt are all related in that they employ a cationic ammonium group in the polymer chain that the active ingredient ilomastat of Schoenfeldt could be added to the cationic polymers of Batich and one of ordinary skill in the art would have a relatively high expectation of success. From the disclosure of Voorhees one of ordinary skill in the art at the time of applicants claimed invention could have made the claimed combination of GM1489 and the cationic ammonium polymers because GM1489 was disclosed as a well known MMP inhibitor thus it would be obvious to one of ordinary skill in the art that it is interchangeable and equivalent with the MMP inhibitor ilomastat disclosed within Schoenfeldt. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were



known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

### ***Response to Arguments***

Applicant's arguments filed 06/22/2007 have been fully considered but they are not persuasive. Applicants assert that the secondary references cited by the examiner would only be combined upon hindsight and the subject matter would not have been obvious at the time of the invention was made to a person of ordinary skill in the art.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618